UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

IN RE K-V PHARMACEUTICAL COMPANY SECURITIES LITIGATION) No. 4:11CV01816 AGF

MEMORANDUM AND ORDER

This consolidated securities fraud class action is before the Court on Defendants' motion to dismiss Plaintiffs' amended complaint for failure to state a claim. Oral argument was held on the motion on November 25, 2013. For the reasons set forth below, the motion to dismiss shall be granted without prejudice to Plaintiffs' filing a second amended complaint with respect to a limited issue.

BACKGROUND

Defendants are K-V Pharmaceutical Company and three of its officers (collectively, "K-V"). The putative class of Plaintiffs consists of all purchasers of publicly traded securities of K-V between February 14, 2011, and April 4, 2011. This litigation is based on allegedly materially false and misleading statements and omissions made by K-V during the class period regarding K-V's distribution and sale of the prescription medicine Makena.

For purposes of the motion now before the Court, the record establishes the following.[1] K-V is a specialty-branded pharmaceutical marketing company that

[1] In the context of securities fraud litigation, facts outside the complaint may be considered where the "complaint quotes selectively from various reports by investment analysts" and the plaintiff does not "challenge the authenticity of the analyst reports attached to defendants' motion to dismiss and cited in plaintiffs' complaint." *Cozzarelli v. Inspire Pharms. Inc.*, 549 F.3d 618, 625 (4th Cir. 2008).

primarily focuses on women's health care. On January 22, 2008, K-V acquired the rights to a drug called Gestiva (formerly known by its generic name 17P), a drug to reduce the risk of pre-term birth for at-risk women. K-V rebranded the drug Makena and applied to the Food and Drug Administration ("FDA") for exclusive sales rights under the Orphan Drug Act ("ODA"). The ODA provides seven years of patent-like exclusive sales rights to manufacturers who win FDA approval for drugs that affect fewer than 200,000 people. The ODA was enacted to encourage drug manufacturers to develop drugs for the treatment of rare diseases or disorders that affect only small patient populations. 21 U.S.C. § 360aa-360ee.

On February 3, 2011, the FDA granted K-V's request for exclusive sales rights for Makena under the ODA. On February 14, 2011, K-V held a conference call with investors and filed a Form 8-K with the Securities and Exchange Commission ("SEC") incorporating the information discussed in the call. At the beginning of the call, K-V stated as follows:

> [C]ertain information provided on this conference call may contain various forward-looking statements within the meaning of the [PSLRA] and may be based on or include assumptions concerning the Company's operations, future results and prospects. Such statements may be identified by the use of words such as plan, expect, believe, anticipate, intend, will, should, could, potential and other expressions that indicate future events and trends.
>
> All statements that address expectations or projections about the future, including without limitation statements about . . . the Company's strategy for growth, product development, product launches, regulatory approvals, market position . . . and other financial results are forward-looking statements. These statements involve various risks and uncertainties that could cause our actual results to differ materially from those expressed in

> such forward-looking statements. These include the risks and uncertainties under the heading risk factors in our most recent annual report on Form 10-K and other periodic reports filed with the SEC which are available on our website at www.KVPharmaceutical.com and on the SEC's website.
>
> Investors are cautioned not to place undue reliance on such forward-looking statements, as there is no assurance that these matters contained in such statements will occur. The forward-looking statements we make on today's call are based on our beliefs and expectations . . . as of today, February 14, 2011 only. We do not undertake any obligation to revise or update such forward-looking statements.

(Doc. No. 91-2 at 3-4.)

K-V then announced that the FDA had approved Makena. K-V described the benefits this approval would bring to K-V, and K-V's commitment to facilitate access to the drug for all eligible patients. K-V then focused on its plans for the commercialization of Makena, which it hoped would play a key role in K-V's effort to return the company to financial stability and profitability. K-V noted that Makena had been granted "orphan drug status" by the FDA, and informed investors that K-V would charge $1,500 per injection of Makena, and expected that patients would receive approximately 15 to 20 injections for a total of up to $30,000 for treatment.

K-V represented that through a program called Makena Care Connection, it would offer administrative, educational, and financial assistance to patients, stating, "wherever needed, the Makena Care Connection will connect Makena-eligible patients with the appropriate financial and co-pay assistance programs . . . . The Makena Care Connection is fully developed, staffed and ready to process the first Makena prescription." K-V also stated:

> We anticipate that some patients may need financial assistance, and we have established a comprehensive patient assistance program to help facilitate access to Makena through the Makena Care Connection. Exemplifying our commitment to patient access, our comprehensive financial assistance program covers both uninsured and insured patients based on income eligibility requirements. Specifically, women with household incomes up to $100,000 will be eligible for financial assistance. And notably, this income level includes approximately 85% of US households.

Id. at 8.

K-V also stated that it anticipated that health insurers and Medicaid would cover the cost of Makena because the costs of a pre-term birth were significantly higher – approximately $51,000. *Id.*

K-V was asked, "could you talk a little bit more about what the strategy is to get the off-label compounding pharmacies off the market? Is that something you have to do, or is that something the FDA will help you in doing?" K-V responded, in relevant part, as follows:

> [W]e believe that the regulations and laws are very clear. I think it's fair to say that compounding pharmacies are not FDA-approved manufacturing facilities and that FDA regulations and state pharmacy laws generally prohibit the distribution of compounded products that are the same or essentially the same as FDA-approved products.
>
> We also believe that compounded pharmacies are aware of these laws and regulations, and our expectation is that they will adhere to them. I think it's also fair to say that, despite the availability of compounded product, there have been moms on the sidelines because of significant logistical and financial barriers to access that are typically associated with non-FDA-approved products.
>
> And I'll just close by saying that everything we have designed around Makena is to remove these barriers and to make sure that we fulfill our

> corporate commitment, which is to make Makena accessible to all eligible patients.

Id. at 13-14.

The same questioner asked: "How many patients, also, do you think you can target in 2011 with this expanded sales force? Do you have an internal goal?" K-V responded:

> We certainly believe, in terms of how we are structuring our go-to-market strategy with our sales force and whatnot puts us in a position to reach out to a requisite number of healthcare professionals to surround the major majority of the business opportunities that exist. . . . [W]e have established a clear objective strategically that we believe that this product, Makena, this treatment, is so important that we need to do everything we can to ensure every eligible mom has access and an opportunity to be treated . . . .

Id. at 13.

In response to a question about the $1,500 per-injection price, K-V stated, "we've done a lot of homework around this particular decision. And we believe our pricing approach is supported by a very comprehensive market research plan which included all stakeholders." K-V again stated that it believed that, in light of the high cost of a pre-term birth, Medicaid and private insurers would cover the drug at the planned price. *Id.* at 14-15.

Among the 30 non-exclusive risk factors that K-V listed in the Form 10-K that had been filed on December 23, 2010, and that was referenced at the beginning of the February 14, 2011 conference call, were the following: "new product development and launch, including the possibility that any product launch may be . . . unsuccessful,

including with respect to Gestiva™"; "acceptance of and demand for our new pharmaceutical products, including Gestiva™"; "the possibility that any period of exclusivity may not be realized, including with respect to Gestiva™, a designated Orphan Drug"; "the regulatory environment, including regulatory agency . . . actions and changes in applicable law or regulations . . . ."; and "the impact of competitive response to our sales, marketing and strategic efforts, including introduction or potential introduction of generic or competing products against products sold by us . . . including Gestiva™, and including competitive pricing changes." (Doc. No. 91-1 at 4-5.)[2]

It is undisputed that K-V pursued Makena "as a lifeline" when the company was in distress, and that Makena's success was of critical importance to the company's survival. Plaintiffs allege that K-V had been told by three former high-ranking employees who are confidential witnesses ("CW") in this case, that if Makena were priced at $1,500 per injection, which represented a 14900% increase from the price at which compounding pharmacies had previously offered a version of the drug, the FDA would not enforce K-V's exclusivity rights, and the marketing of Makena would be harmed, as well as its relationships with organizations that were proponents of Makena, such as the March of Dimes.

Plaintiffs also allege that months before the investor conference call, K-V held a session to train its sales representatives to deal with the anticipated negative pushback

[2] Plaintiffs do not argue that reference to Gestiva is different in any relevant way from reference to Makena.

related to Makena's pricing at $1,500 per injection. According to another CW who was at the meeting, the whole sales team was shocked by the planned price for Makena.

On February 17, 2011, K-V sent a letter to compounding pharmacies, stating that unapproved formulations of Makena "should no longer be made by compounding pharmacies" and that "as articulated by the FDA in numerous enforcement actions," the FDA's enforcement "discretion does not extend to compounding of copies or essentially copies of commercially available FDA-approved products," and that if the compounding pharmacies continued to manufacture the equivalent of Makena, they would be "subject to FDA enforcement."

On March 8, 2011, K-V issued a press release announcing that Makena would become available for prescribing during the week of March 14, and described its financial assistance program. On the same day K-V filed a Form 8-K with the SEC, in which K-V projected that current assets would increase from approximately $31 million as of March 31, 2010, to over $1.2 billion in March 2013. K-V stated that the projected "increase in current assets beginning in March 2011 is primarily due to receivables associated with sales launch of Makena™." The report then noted that "[a]lthough Makena™ is the first and only FDA-approved treatment indicated to reduce the risk of preterm birth in [at risk] women . . . , the Company's sales of Makena™ could be negatively affected by treatment of this condition by unapproved drug therapies," and that "[a]ctual sales volumes for Makena™ will depend on a number of factors, including market acceptance." (Doc. No. 91-4.)

Makena was released to the public as planned. After the Makena pricing structure was revealed, the March of Dimes withdrew the support it had previously given to K-V and refused to allow K-V to use the March of Dimes' name in association with the drug. On March 17, 2011, two United States Senators issued a press release expressing concern over the list price for Makena and the insufficiency of K-V's financial assistance program, stating that "the financial assistance is not sufficient and does not expand to certain groups of women." They also released a letter they had sent to the FTC urging an investigation, and that same day, one of the Senators voiced these concerns at a Senate appropriations hearing. The price of KV's Class A common stock dropped from an opening price of $9.75 on March 17, 2011, to a closing price of $8.50 on March 18, 2011.

On March 30, 2011, the FDA issued a statement that the FDA did not intend to take enforcement action against pharmacies that compounded the equivalent of Makena. The statement provided, in relevant part, as follows:

> FDA understands that the manufacturer of Makena, KV Pharmaceuticals, has sent letters to pharmacists indicating that FDA will no longer exercise enforcement discretion with regard to compounded versions of Makena. This is not correct.
>
> In order to support access to this important drug, at this time and under this unique situation, FDA does not intend to take enforcement action against pharmacies that compound [the chemical equivalent to Makena] based on a valid prescription for an individually identified patient unless the compounded products are unsafe, of substandard quality, or are not being compounded in accordance with appropriate standards for compounding sterile products. As always, FDA may at any time revisit a decision to exercise enforcement discretion.

(Doc. No. 91-8 at 2.)

On April 1, 2011, K-V announced that it was reducing Makena's list price to $690 per injection. The price of K-V Class A common stock continued to decline. The closing price of KV's Class A common stock on April 4, 2011 was at $5.00, a drop of over 28% from the stock's price of $6.95 at the opening of the markets on March 30, 2011.

The present action was filed on October 19, 2011. The gravamen of Plaintiffs' claims is that K-V knew or should have known that if it charged $1,500 for Makena without an effective financial assistance program, Makena would not be commercially successful, in large part because the FDA would not enforce K-V's exclusive rights to manufacture and distribute Makena. According to Plaintiffs, the omission of this risk rendered many of K-V's above-quoted statements during the February 14, 2011 investor conference call materially false and/or misleading, in violation of Section 10(b) of the Securities Exchange Act of 1934, as amended by the Private Securities Litigation Reform Act ("PSLRA"), and Rule 10b-5 promulgated thereunder by the SEC.

More specifically, Plaintiffs allege that K-V's statements related to its commitment to ensure access to Makena to every eligible patient, working in concert with stakeholders to fulfill that commitment, establishing a comprehensive patient financial assistance program, and building a go-to-market strategy were materially misleading. Plaintiffs allege that K-V's statement that it anticipated health insurers would cover the cost of Makena were materially false and/or misleading because K-V knew that the $1,500 per dose price "would face opposition at all levels."

Plaintiffs allege that K-V's statements regarding its planned efforts to facilitate

access to Makena for every eligible patient and "working in concert with stakeholders to help ensure that all eligible patients have access" were materially misleading because K-V was aware that Makena's list price would not facilitate access for every available patient, the financial assistance provided through Makena Care Connection was inadequate because it did not extend to certain groups of women, and Defendants ignored the March of Dimes in their marketing approach for Makena.

The allegation regarding K-V's knowledge is based on the CWs' warnings, the training session for K-V's sales people, and the fact that the financial assistance program offered by K-V was "patently inadequate" and "woefully insufficient." On this last point, Plaintiffs allege as follows: "CW1 stated that a third party organization handled Makena Care Connection, that it was the worst program he/she had ever seen, and it was a 'tremendous screw up' that was not set up to deliver what the public had been promised by Defendants." (Doc. No. 67 at 9.)

Plaintiffs also assert that the March 8, 2011 Form 8-K contained revenue assumptions which were "unreasonable and had no basis in fact" because they did not account for the public reaction to Makena's price and the actions of compounders.[3]

[3] On July 5, 2012, K-V Pharmaceutical Co. sued the FDA in the Federal District Court for the District of Columbia, alleging that the FDA (and related parties) violated the ODA by failing to take action against compound pharmacies that created a cheaper alternative to Makena. K-V Pharmaceutical Co. sought declaratory and injunctive relief. On September 6, 2012, the court granted the defendants' motion to dismiss, holding that the FDA's decision was judicially unreviewable. *K-V Pharm. Co. v. FDA*, 889 F. Supp. 2d 119, 132-35 (D.D.C. 2012). On January 7, 2014, the Court of Appeals for the District of Columbia, in a summary opinion, vacated the district court's decision and remanded the case for

On August 6, 2012, K-V Pharmaceutical Co. filed for bankruptcy and the Court entered a stay in the present case with respect to that Defendant. The motion to dismiss now under consideration was filed by the three individual Defendants. K-V Pharmaceutical Co. joined in the motion after it emerged from bankruptcy and the Court lifted the bankruptcy stay that had been entered.

ARGUMENTS OF THE PARTIES

K-V first argues that the amended complaint should be dismissed because the challenged statements made to investors during the February 14, 2011 investor conference call, including statements about a comprehensive patient financial assistance program, and the revenue projections in the March 8, 2001 Form 8-K, were forward-looking statements that are not actionable, pursuant to the "safe harbor" provision of the Private Securities Litigation Reform Act of 1995 ("PSLRA"), 15 U.S.C. § 78u–5(c). This provision protects forward-looking statements that were accompanied by meaningful risk disclosures.

With regard to statements about patient access, K-V points to the disclosure of the following risk factors: "new product . . . launch, including the possibility that any product launch may be . . . unsuccessful, including with respect to Gestiva™" and the "acceptance of and demand for the Company's new pharmaceutical products, including Gestiva™." With regard to statements about exclusivity and insurance coverage, K-V

---

reconsideration in light of *Cook v. FDA*, 733 F.3d 1 (D.C. Cir. 2013) (explaining the narrow scope of an agency's judicially unreviewable discretion), and the Drug Quality and Security Act, Pub. L. No. 113–54, 127 Stat. 587 (2013). *K-V Pharm. Co. v. FDA*, No. 12-5349, 2014 WL 68499, at *1 (D.C. Cir. Jan. 7, 2014).

points to the disclosure of the following risk factors: "the possibility that any period of exclusivity may not be realized, including with respect to Gestiva™"; "the impact of competitive . . . response . . . to the Company's sales . . . including introduction or potential introduction of generic or competing products . . . against products sold by us . . . , including Gestiva, and including competitive or responsive pricing changes"; "reimbursement policies of third parties may affect the marketing of our products"; and "[o]ur ability to market our products will depend in part on reimbursement levels for the cost of the products and related treatment established by health care providers, including government authorities, private health insurers and other organizations."

K-V argues that the statements in the February 17, 2011 letter to compounding pharmacies are not actionable because they were not made to the investing public. K-V next argues that even if K-V's challenged statements are actionable, Plaintiffs have failed to allege facts that meet the PSLRA pleading standards for falsity, materiality, and scienter. First, according to K-V, the amended complaint does not demonstrate that the statements were false; rather, the statements accurately summarized the FDA's regulations and enforcement policies, and accurately described K-V's plans to promote access to Makena and K-V's anticipated revenues.

Specifically with regard to K-V's statements about the financial assistance it would provide to low-income patients, K-V argues that Plaintiffs' allegations that K-V's assistance plan was insufficient lack any factual support. Additionally these statements were "immaterial to investors because a reasonable investor would not choose to

purchase K-V's stock because it committed to giving away large amounts of free and discounted product." And the statements about facilitating access for every eligible patient were "immaterial puffery." (Doc. No. 91 at 28-30.)

K-V next argues that Plaintiffs did not allege facts that give rise to the requisite "strong inference" of scienter, or wrongful intent, in that the opinions of the CWs merely show disagreement with management over pricing. K-V maintains that it could not foresee that the FDA would decide not to enforce K-V's exclusive rights against compounding pharmacies due to political pressure. According to K-V, "Plaintiff's supposed inference of fraud is highly improbable compared to the far more compelling inference that Defendants believed K-V could successfully market Makena and that their business judgment was that the best way to do so was by selling Makena at the list price of $1,500 per injection with a patient financial assistance program." (Doc. No. 91 at 34.)

Plaintiffs begin their argument by pointing to K-V's past misdeeds that led to sizeable fines for criminal fraud and the decline in the company's assets. It is undisputed that this made Makena's success crucial to the company's survival. Plaintiffs assert that the FDA's refusal to enforce Makena's exclusivity was a foreseeable result of the drug's high price, and that K-V was specifically warned by the CWs about this "likely result." Plaintiffs argue that the amended complaint adequately alleges that K-V's challenged statements were materially false and misleading when made. For example, Plaintiffs maintain that the statements that "FDA regulations and state pharmacy laws generally prohibit the distribution of compounded products that are the same or essentially the

same as FDA-approved products" and "[w]e also believe that compounded pharmacies are aware of these laws and regulations, and our expectation is that they will adhere to them," had no basis in fact, because one of the CWs told K-V that if it charged $1,500 per injection, the FDA would not preclude compounding pharmacies from producing the drug. They also argue that K-V's statements in the February 17, 2011 letters to pharmacists are actionable because it was plausible that the letter would reach the investing public.

Plaintiffs raise similar arguments with respect to statements about patient access to, and marketing efforts of, Makena. They assert that the amended complaint "plausibly alleges that statements regarding Makena Care Connection's ability to ensure patient access were false because it did not extend to certain groups of women." (Doc. 95 at 20 & n. 8.) In support of this argument, Plaintiffs cite the March 17, 2011 press release by the two Senators.

Plaintiffs argue that the safe harbor provision is not applicable to the statements regarding patient access and marketing because these statements were not forward-looking or accompanied by meaningful cautionary language. According to Plaintiffs, in light of the CWs' opinions that the FDA would not enforce exclusivity if Makena were priced as planned, the cautionary language had to warn of that specific risk of nonenforcement.

Plaintiffs argue that K-V's scienter in not disclosing the specific risk of nonenforcement by the FDA due to the planned price for Makena is sufficiently pled in

light of the warnings by the CWs, and K-V's acknowledging in its training session with salespeople that the high price of the drug would be an issue with consumers. Plaintiffs ask the Court for leave to file a second amended complaint, should the Court decide that the present complaint fails to state a claim. At oral argument, Plaintiffs suggested that with more time, they might be able to amend the complaint to allege that the CWs knew, rather than just thought, that the FDA would not enforce Makena's exclusivity if K-V proceeded to charge $1,500 per injection.

DISCUSSION

To survive a motion to dismiss, a complaint must contain sufficient factual matter, which, if accepted as true, states "'a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). Although a complaint need not contain "detailed factual allegations," it must contain facts with enough specificity "to raise a right to relief above the speculative level." *Twombly*, 550 U.S. at 555. "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements," will not pass muster. *Iqbal*, 556 U.S. at 678. In sum, this standard "calls for enough fact to raise a reasonable expectation that discovery will reveal evidence of [the claim]." *Twombly*, 550 U.S. at 556.

The reviewing court must accept the plaintiff's factual allegations as true and construe them in the plaintiff's favor, but is not required to accept the legal conclusions the plaintiff draws from the facts alleged. *Iqbal*, 556 U.S. at 678; *see also Retro Television Network, Inc. v. Luken Commc'ns, LLC*, 696 F.3d 766, 768-69 (8th Cir. 2012).

The court must '"draw on its judicial experience and common sense,'" and consider the plausibility of the plaintiff's claim as a whole, not the plausibility of each individual allegation. *Zoltek Corp. v. Structural Polymer Grp.*, 592 F.3d 893, 896 n.4 (8th Cir. 2010) (citation omitted).

"Section 10(b) and Rule 10b-5 prohibit fraudulent conduct in the sale and purchase of securities." *McAdams v. McCord*, 584 F.3d 1111, 1113 (8th Cir. 2009). To state a private securities fraud claim under Section 10(b) and Rule 10b–5, a plaintiff must allege "(1) a material misrepresentation (or omission); (2) scienter, *i.e.*, a wrongful state of mind; (3) a connection with the purchase or sale of a security; (4) reliance, often referred to in cases involving public securities markets (fraud-on-the-market cases) as transaction causation; (5) economic loss; and (6) loss causation, *i.e.*, a causal connection between the material misrepresentation and the loss." *Horizon Asset Mgmt. Inc. v. H & R Block, Inc.*, 580 F.3d 755, 760 (8th Cir. 2009) (citations omitted).

The PSLRA dictates special heightened pleading rules for securities fraud cases, intended to eliminate abusive securities litigation and put an end to the practice of pleading fraud "by hindsight." *In re K-tel Int'l, Inc. Sec. Litig.*, 300 F.3d 881, 889 (8th Cir. 2002). This standard requires plaintiffs to specify each misleading statement or omission and specify why the statement or omission was misleading. 15 U.S.C. § 78u–4(b)(1). The complaint must also "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." *Id*. § 78u–4(b)(2).

Pleadings falling short of the PSLRA's heightened standard "shall" be dismissed. *Id.* § 78u–4(b)(3)).

"While materiality is generally a question of fact reserved for the jury, alleged misrepresentations are immaterial as a matter of law where a court determines that no reasonable investor could have been swayed by the alleged misrepresentation." *In re Amdocs Ltd. Sec. Litig.*, 390 F.3d 542, 547 (8th Cir. 2004) (citation omitted). "A misrepresentation or omission is material if there is a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the total mix of information made available." *Id.* at 548 (citation omitted).

The Safe Harbor

The PSLRA contains a "safe harbor" exception, which states that in any private action based on an untrue statement of material fact or omission of a material fact, a defendant will not be liable for making a "forward-looking statement" that is (1) "identified as a forward-looking statement, and is accompanied by meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the forward-looking statement"; (2) immaterial; or (3) made without actual knowledge that the statement was false or misleading. 15 U.S.C. § 78u–5(c)(1, 2).

The Act defines six exclusive categories of forward-looking statements:

> (A) a statement containing a projection of revenues, income (including income loss), earnings (including earnings loss) per share, capital expenditures, dividends, capital structure, or other financial items;

> (B) a statement of the plans and objectives of management for future operations, including plans or objectives relating to the products or services of the issuer;
>
> (C) a statement of future economic performance, including any such statement contained in a discussion and analysis of financial condition by the management or in the results of operations included pursuant to the rules and regulations of the Commission;
>
> (D) any statement of the assumptions underlying or relating to any statement described in subparagraph (A), (B), or (C);
>
> (E) any report issued by an outside reviewer retained by an issuer, to the extent that the report assesses a forward-looking statement made by the issuer; or
>
> (F) a statement containing a projection or estimate of such other items as may be specified by rule or regulation of the Commission.

15 U.S.C. § 78u–5(i)(1).

To decide whether a statement is forward-looking, "the determinative factor is not the tense of the statement; instead, the key is whether its truth or falsity is discernible only after it is made." *W. Wash. Laborers-Emp'rs Pension Trust v. Panera Bread*, 697 F. Supp. 2d 1081, 1093 (E.D. Mo. 2010) (citation omitted).

In order for accompanying cautionary statements to trigger protection under the safe harbor, they must be "substantive company-specific warnings based on a realistic description of the risks applicable to the particular circumstances, not merely a boilerplate litany of generally applicable risk factors." *Southland Sec. Corp. v. INSpire Ins. Solutions, Inc.*, 365 F.3d 353, 372 (5th Cir. 2004); *see also Rabbani v. DryShips Inc.*, No. 4:12CV130 RWS, 2012 WL 5395787, at *13 (E.D. Mo. Nov. 6, 2012) ("The

cautionary language must relate directly to that by which plaintiffs claim to have been misled.").

With regard to oral forward-looking statements, the safe harbor provision explicitly provides that a written, identified, and "readily available document" may be incorporated by reference. 15 U.S.C. § 78u–5(c)(2)(B). Any document either "filed with the Commission or generally disseminated shall be deemed to be readily available." 15 U.S.C. § 78u–5(c)(3); *see also Rabbani*, 2012 WL 5395787 at *5.

The applicability of the safe harbor is a question of law. 15 U.S.C. § 78u-5(e) ("On any motion to dismiss based upon [the safe harbor], the court shall consider any statement cited in the complaint and any cautionary statement accompanying the forward-looking statement, which are not subject to material dispute . . . ."). Several courts in this District have held that a forward-looking statement is protected if it is immaterial or identified as forward-looking and is accompanied by meaningful cautionary language, regardless of whether the speaker knows the statement is false. *See Rabbani*, 2012 WL 5395787 at *4; *Rochester Laborers Pension Fund v. Monsanto Co.*, 883 F. Supp. 2d 835, 854 (E.D. Mo. 2012); *W. Wash. Laborers–Emp'rs Pension Trust v. Panera Bread Co.*, No. 4:08CV00120 ERW, 2009 WL 3756619, at *2-3 (E.D. Mo. Nov. 6, 2009). This Court adopts this position on the matter.

The Court first concludes that the bulk of K-V's challenged statements were forward-looking and were accompanied by meaningful cautionary language. Plaintiffs are right that "a boilerplate litany of generally applicable risk factors," will not suffice,

see Southland Sec. Corp. v. INSpire Ins. Solutions, Inc., 365 F.3d 353, 372 (5th Cir. 2004), but here the standard for "meaningful" is met, most notably by, but not limited to, the following risks listed in the Form 10-K mentioned above: "new product . . . launch, including the possibility that any product launch may be . . . unsuccessful, including with respect to Gestiva™," the "acceptance of and demand for the Company's new pharmaceutical products, including Gestiva™," and "the possibility that any period of exclusivity may not be realized, including with respect to Gestiva™ . . . ." *See, e.g.*, *Emp'rs Teamsters Local Nos. 175 & 505 Pension Trust Fund v. Clorox Co.*, 353 F.3d 1125, 1132-33 (9th Cir. 2004) (holding that safe harbor provision applied to company officer's allegedly misleading statement that it would take approximately one year for company to resolve problems created by acquisition of another company where officer preceded statement with broadly worded caution and referred analysts to company's Form 10-K which disclaimed assurance that company would be able to successfully integrate acquisition into its operations).

The sole exception relates to K-V's statements in the investor call about the financial assistance program K-V would be offering in connection with Makena. An argument can be made that these statements were not forward looking; rather the statements were about a present program to be implemented in the future. The Court will accordingly consider whether Plaintiffs have met the pleading standards with regard to these statements, as well as with regard to the challenged omission: K-V's failure to disclose the risk of nonenforcement associated with the high price for the drug.

Falsity, Materiality, and Scienter

With respect to K-V's statements about its financial assistance program for patients who could not afford Makena at the $1,500 per injection price, the Court concludes that the amended complaint does not meet the PSLRA's standards for alleging that the statements were false or misleading. Plaintiffs do not state what financial assistance K-V offered and how this would not expand access to Makena for lower-income patients. The conclusory allegations that the financial assistance plan was "patently inadequate" do not "provide an adequate basis for believing that [K-V's] statements were false." *See Applestein v. Medivation, Inc.*, ___ F.3d ___, 2014 WL 892900, at *2 (9th Cir. 2014). Nor do Plaintiffs provide any factual basis for Defendants' alleged knowledge that the financial plan was inadequate. The allegation in the complaint that one CW expressed that belief does not suffice under the PSLRA.

If these statements regarding the financial assistance program were false, an argument could possibly be made that the other elements of a claim under Section 10(b) and Rule 10b-5 with respect to these statements could be adequately pled, not, as will be discussed below, with respect to the FDA's subsequent actions, but with respect to Makena's commercial viability in general. As such, the Court will allow Plaintiffs 20 days from the date of this Memorandum and Order to file a new amended complaint covering this matter. If they do so, K-V shall have 20 days thereafter to answer or otherwise respond.

With respect to the allegation that K-V did not disclose a risk that the FDA would not enforce K-V's exclusive rights to Makena, the Court concludes that even if the omission were not protected by the safe harbor, Plaintiffs have failed sufficiently to plead scienter in this regard, which, as noted above, is an element of a cause of action under Section 10(b) and Rule 10b-5. To establish scienter, a plaintiff must prove that the defendant acted with "a mental state embracing intent to deceive, manipulate, or defraud." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 319 (2007). Scienter can be established in one of three ways: "(1) from facts demonstrating a mental state embracing an intent to deceive, manipulate, or defraud; (2) from conduct which rises to the level of severe recklessness; or (3) from allegations of motive and opportunity." *Detroit Gen. Ret. Sys. v. Medtronic, Inc.*, 621 F.3d 800, 808 (8th Cir. 2010). "The inquiry . . . is whether *all* of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard." *Tellabs, Inc.*, 551 U.S. at 322-23.

"[I]n determining whether the pleaded facts give rise to a 'strong' inference of scienter, the court must take into account plausible opposing inferences." *Id.* at 323. "[A]n inference of scienter can only be strong . . . when it is weighed against the opposing inferences that may be drawn from the facts in their entirety." *Cozzarelli v. Inspire Pharm. Inc.*, 549 F.3d 618, 624 (4th Cir. 2008). "A court must compare the malicious and innocent inferences cognizable from the facts pled in the complaint, and only allow the complaint to survive a motion to dismiss if the malicious inference is at

least as compelling as any opposing innocent inference." *Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 991 (9th Cir. 2009). "A complaint will survive . . . only if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged." *Telltabs, Inc.*, 551 U.S. at 324.

Here, the Court concludes that Plaintiffs' reliance on the CWs' alleged statements regarding the FDA's future actions to establish K-V's scienter fails. To support an allegation of scienter in this context, the statements of CWs "may be relied on only where the CWs are described with sufficient particularity to support the probability that a person in the position occupied by the source would possess the information alleged, and the complaint provide[s] an adequate basis for determining that the witnesses in question have personal knowledge of the events they report." *Applestein*, 2014 WL 892900, at *2 (citation omitted); *see also In re St. Jude Med., Inc. Sec. Lit.*, 836 F. Supp. 2d 878, 900 (D. Minn. 2011) (holding that at the pleading stage, investors could rely on CWs to establish the defendant's scienter where the complaint showed that the CWs were persons who "were in a position to know at first hand the facts to which they are prepared to testify").

Here, the amended complaint does not allege sufficient facts from which the Court could conclude that the CWs knew or were in a position to know that the FDA would not, or very likely would not, enforce Makena's exclusivity rights under the ODA, such as to create a compelling inference of scienter on K-V's part. Such knowledge on the part of

the CWs seems improbable in light of the FDA's own statement that its decision was based on a "unique situation." Further, on these facts, the Court cannot conclude that a malicious inference is as compelling as an innocent one–namely, that Defendants made a pricing decision that, in hindsight, proved to be quite poor.[4]

As noted above, Plaintiffs suggested at oral argument that if given some time to explore the matter, they could possibly find a factual basis to support further amendment to the complaint to allege that one or more of the CWs had such knowledge. Pursuant to Federal Rule of Civil Procedure 15(a)(2), courts should grant leave to amend a pleading "freely . . . when justice so requires." Here Plaintiffs have had ample opportunity to fully explore what the CWs knew and the basis for their supposed knowledge. By the time of oral argument, the case had been pending for over two years. The CWs are Plaintiffs' own witnesses to whom they had access at least since the filing of the amended complaint in July 2012. And given the questionable ability of Plaintiffs to establish K-V's required scienter based on the CWs, the Court does not believe that giving Plaintiffs leave at this point in the proceedings to amend their current complaint regarding this particular claims is warranted. This is especially true inasmuch as the Court finds K-V's statements with regard to FDA enforcement of exclusivity to be protected forward-looking statements.

Except as set forth above, with respect to K-V's statement about its financial assistance program for Makena, Plaintiffs' more general request for leave to file a second amended complaint should the Court decide that the present complaint fails to state a

[4] Plaintiffs have not suggested that Defendants had any financial incentive to represent their belief as to exclusivity if they knew it to be untrue.

claim shall also be denied. *See, e.g., Minneapolis Firefighters' Relief Ass'n v. MEMC Elec. Materials, Inc.*, 641 F.3d 1023, 1030 (8th Cir. 2011) (holding that the district court did not err in denying motion for leave to amend a securities fraud complaint where in opposition to the defendants' motion to dismiss, the plaintiff asked the court for leave to amend the complaint "if the Court finds that the Complaint is deficient in any respect") (citing cases).

Plaintiffs do not allege that any corporate executive personally benefitted from the asserted non-disclosure of the risk of nonenforcement and this supports a finding of no scienter. *See id.* Plaintiffs' reliance on K-V's training sessions to establish a strong inference of scienter is also unavailing. The sessions reveal no more than that K-V knew that the $1,500 per injection price might cause "push back" from consumers. But this does not suggest that K-V knew that there was a risk that the FDA would not enforce Makena's ODA exclusivity due to the price and hid that knowledge with the intent to deceive investors.

Plaintiffs cite to *Public Pension Fund Group v. KV Pharmaceutical Co.*, 679 F.3d 972 (8th Cir. 2012), in opposition to K-V's motion to dismiss. In that case, investors brought a class action against K-V Pharmaceutical Co. and its officers alleging that the defendants violated federal securities laws by issuing false and misleading statements regarding the company's compliance with FDA regulations and its financial condition. The investors based this claim on K-V Pharmaceutical Co.'s knowledge of the results of a series of inspections the FDA made of K-V Pharmaceutical Co.'s facilities between

2003 and 2009. The FDA reported the results of its inspections to K-V Pharmaceutical Co. on Form 483s which is pursuant to FDA regulations to notify a company's top management in writing of significant objectionable conditions, relating to products and/or processes, or other violations of federal law which were observed during an inspection. The Eighth Circuit held the FDA's issuance of Form 483s might have rendered K-V Pharmaceutical Co.'s statement about its compliance with FDA regulations false, or at least misleading. Accordingly, the case was remanded for further proceedings.

Here, the challenged statement by K-V cannot be compared to the issuance by the FDA of the Form 483s, in terms of rendering any of K-V's challenged representations or omissions false or misleading when made. Lastly, the allegations in the amended complaint about K-V's recent wrongdoing unrelated to Makena have no relevance to whether the allegations of wrongdoing alleged in the present complaint state a claim.

CONCLUSION

Accordingly,

IT IS HEREBY ORDERED that Defendants' motion to dismiss is **GRANTED** without prejudice to Plaintiffs filing a second amended complaint within 20 days of this Memorandum and Order, consistent with the discussion above. (Doc. No. 90.)

Audrey G. Fleissig

AUDREY G. FLEISSIG
UNITED STATES DISTRICT JUDGE

Dated this 27th day of March, 2014.